EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. BIOPURE CORPORATION, THOMAS MOORE, HOWARD RICHMAN, and JANE KOBER Defendants.	)	CIVIL ACTION N0. 05-11853 - PBS

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

In their motion for partial summary judgment, Defendants request that the Court conduct a simple act of judicial review: compare the letter dated July 30, 2003 received from the Food and Drug Administration, regarding Biopure's Biologics License Application, to the Company's press release about that letter dated August 1, 2003. That comparison compels partial summary judgment for Defendants on all claims about the press release.

I. Plaintiff's Contentions About Omissions Are Not Actionable.

Plaintiff contends that three omissions make the press release fraudulent: (1) the press release failed to mention "serious concerns" about Biopure's submission, pp. 7-9, and "extensive questions" about data, pp. 13, 14; (2) the press release failed to disclose that the July 30 BLA letter was allegedly a "Complete Response Letter," pp. 14-17; and (3) the press release failed to disclose a different letter dated July 30, 2003 about a proposed protocol for a different indication, not the BLA for orthopedic surgery. Pp. 17, 18.

A. Serious Concerns and Extensive Questions Are Characterizations, Not Facts.

The press release reported that the letter requested "additional information" and that the letter "focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling." *See* Transmittal Affidavit of Robert A. Buhlman filed with Defendants' Motion for Partial Summary Judgment, Ex. A. As evidence that the July 30 BLA Letter does just that, the Letter reads: "please comment" - 26 times; "please explain" - 36 times; "please clarify" - 8 times; and "please describe" - 5 times.[1] July 30 BLA Letter, Buhlman Aff. Ex. E (hereafter, the "Letter"). The Letter requests seven lists, seven spreadsheets and four flow diagrams. The Letter refers to these as "the above steps for approval" and invites a meeting to discuss them. Letter, p. 34.

Plaintiff contends the press release was misleading because *the SEC contends* the FDA's questions were "negative comments," p. 7, "sharply criticized" Biopure's submission, p. 7, and were "not good news." P. 9

The July 30 BLA Letter does not say anywhere that it is "negative," "sharply critical" or "not good news." Plaintiff's characterizations are not facts -- they are litigious arguments. They should be disregarded by the Court in favor of what the Letter actually *says*. *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 375-77 (3rd Cir. 1993), *cert. denied*, 510 U.S. 1178 (1994) (securities laws are concerned with disclosure of facts, not with the failure to characterize facts with pejorative adjectives); *Kowal v. MCI Communications Corp.*, 16 F.3d 1271, 1277 (D.C. Cir. 1994) ("Since the use of a particular pejorative adjective will not alter the total mix of information available to the investing public, such statements are immaterial as a matter of law and cannot serve as the basis of a 10b-5 action under any theory.")

[1] Plaintiff cannot seriously contend that it is securities fraud to use the phrase "clarification of clinical and preclinical data" instead of the phrase "explanations of, comments on and clarification of" data.

Plaintiff concedes "defendants did not need to communicate every single issue raised by the FDA, nor did they need to characterize the FDA's concerns." Opposition, p. 9. The case law establishes that proposition as well. *In re PLC Systems Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 119 (D. Mass. 1999). Thus, it is not actionable because the Letter did not disclose the details of how many questions or what data clarifications were requested.

Plaintiff also concedes that "it was literally true that FDA did not request additional clinical trials." Opposition, p. 13. What follows in the Opposition about why that was a "half truth" is simply a reiteration that the Letter contained *questions*. Opposition, p. 13 ("Letter contained extensive questions about the integrity and reliability about data."). The Letter did not request additional clinical trials -- fact -- and that is what the press release said -- fact. The specific data questions did not need to be disclosed.[2]

Plaintiff relies on three cases. However, by their distinctions, these cases actually show why defendants are entitled to partial summary judgment on the press release claims:

1. *In re Transkaryotic Therapies, Inc.*, 319 F. Supp. 2d 152 (D. Mass. 2004).

   In this case, a decision on a motion to dismiss, not for summary judgment, shareholder plaintiffs alleged that the letter in question "stated bluntly and at length" that both clinical tests "failed to demonstrate efficacy." *Id.* at 156. Moreover, the letter allegedly stated "we recommend that you conduct additional clinical studies and submit the results to CBER." The Court noted this request could well have "amount[ed] to years of additional research." *Id.* at 161. The July 30 BLA Letter, which this Court can read on summary judgment, does *not* "state bluntly and at length" that the tests "failed to demonstrate" safety or efficacy and it does *not* recommend additional clinical trials.

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[2] Remarkably, Plaintiff also cites *testimony* taken in its investigation not about what the Letter *said*, but about what FDA witnesses said to the SEC in their private, cooperative sharing of information. *See* Statement of Facts, ¶70. Clearly, if it was not stated by FDA *to the Company* in the formal written communication, then it is not relevant to the Company's disclosure about the Letter. The testimony cited by Plaintiff is irrelevant. It is also inadmissible. It also is not properly considered under Fed R. Civ. P. 56, because Defendants were not allowed to participate in that private sharing of information within the government. *See Finn v. Consolidated Rail Corp.*, 782 F.2d 13, 16 (1st Cir. 1986); *Berwick Grain Co., Inc. v. Illinois Dept. of Agriculture*, 116 F.3d 231, 234 (7th Cir. 1997) (Interview transcript without affidavit not admissible under Fed. R. Civ. P. 56(e)).

2. *In re Amylin Pharma., Inc. Sec. Litigation*, No. 0lCV1455, 2003 WL 21500525 (S.D. Cal. August 9, 2001).

This case is also a decision on a motion for reconsideration of the District Court's denial of a motion to dismiss. It is not a summary judgment precedent. Furthermore, the allegedly misleading statements were specific statements about clinical results:

> These improvements in glucose were achieved *without an increase in the evidence of hypoglycemic events or clinically important safety issues*.

Id. at *2 (emphasis in the original). Defendant also announced that the clinical trial "is sufficient to support approval," even though plaintiffs alleged that FDA said "current study data is not considered pivotal data for an NDA," meaning it could *not* support a marketing approval. *Id.* at 1, 2. On a motion to dismiss, allegations of specific statements of results that were allegedly misleading in light of actual data or statements allegedly *contradicted* by FDA were upheld at the pleading stage. Here, the press release makes no statement about results and the SEC has not asserted that a *statement about results* was wrong in light of *actual results.*

3. *In re CV Thera. Inc. Sec. Litig.*, No. C 03-30709 2004 WL 1753251 (N.D. Cal. Aug. 5, 2004)

This third case is also a motion to dismiss case. Furthermore, it is also a case where alleged statements "we believe that for Ranolazine (ph) [the QT effect] won't be a particular problem for review by the agency" were contradicted by contemporaneous *facts*. *Id.* at *6. Here, on a motion for summary judgment, there is no statement of fact in the press release that it *contradicted* by the Letter.

What is instructive about these cases -- assertedly Plaintiff's best -- is that they demonstrate the core reason why Defendants deserve judgment. Plaintiff has not alleged that the press release contains a statement of fact that is contradicted by what the July 30 BLA Letter actually *says*.

B. <u>The Complete Response Letter Label Is Not An Actionable Omission</u>.

Plaintiff continues to argue that the August 1 press release was misleading because it did not label the Letter a "Complete Response Letter." Plaintiff concedes, however, as it must, that the Letter does *not* say it is a complete response letter.

The press release said "FDA has completed its review of the company's biologics license application for Hemopure® [hemoglobin glutamer-250 (bovine)] and issued a letter requesting additional information." Thus, the Company used the same phrase as the Letter, "completed the review."

Plaintiff's contention that the label itself is material is contradicted *by the FDA*: "the issuance of complete response letters....[carry] no implication as to the ultimate approvability of the application." *See* Proposed Rules Department Of Health And Human Services: FDA 21 CFR Parts 312, 314, 600, and 601 Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications Tuesday, July 20, 2004 69 FR 43351-01, 2004 WL 1599720.[3] Moreover, it *cannot* be material when it was not in the Letter *and* the press release used the phrase the Letter used: "completed review." "Completed review" and "complete response" carry the same plain meaning.[4]

Plaintiff is left to argue that the label meant something to how long FDA would take to review Biopure's response. Opposition, p. 16. The press release did not *speculate* about how long FDA would have to review Biopure's response. Indeed, Plaintiff's own submission suggests the reason the July 30 Letter arrived 30 days early was because a reviewer was traveling later. Opposition, p. 19. That shows FDA can act when it chooses, for unpredictable reasons. The press release did use the word "suspended" because the July 30 BLA letter said the review clock was "suspended." *See* Letter, p. 34. It cannot be securities fraud to use the FDA's own words in the Letter in a press release about the Letter, especially when the contention is that the

[3] This was included in the Appendix of Citations to Defendants' Memorandum of Law, Ex. 3.

[4] Notably, in *Transkaryotic*, the parties and the Court actually refer to the letter as a "Complete Review Letter." *See, In re Transkaryotic,* 319 F. Supp. at 156. Furthermore, FDA's Manual of Standard Operating Procedures and Policies, SOPP 8405, refers several times to "complete review." *See* SOPP 8405, attached hereto as Exhibit A. (Both parties submitted later versions of this SOPP with their briefs. This version attached as Exhibit A was in effect on July 30, 2003, but it is the same as the later versions on this point.)

press release did not *speculate* about the length of a *future* review period that was not mentioned in the Letter.[5]

C. The Press Release Was Not About The Separate Trauma Indication.

The SEC contends that partial summary judgment should not be granted because the press release about the Company's July 30 BLA Letter did *not* disclose that there was a second letter dated July 30, 2003 about a proposed clinical trial protocol for a different indication (i.e., the trauma protocol). The SEC's contention is off-point. The subject of this motion for partial summary judgment is limited to Biopure's disclosure in the August 1 press release concerning the July 30 BLA Letter and does not concern the disclosure or non-disclosure of the July 30 letter regarding the trauma protocol.

Furthermore, at trial, defendants will demonstrate why the SEC cannot prove its claims for omissions about the trauma protocol. The July 30, 2003 letter about the trauma protocol is about a *different* IND and a *specific protocol* regarding a possible test in trauma patients. *See* SEC Exhibit 49, p. 1 (identifying the specific IND by number and the protocol by name). By regulation a clinical hold applies only to *the specific* IND and specific *trial identified*:

> A clinical hold is an order issued by FDA to the sponsor to delay a proposed clinical investigation.... It will identify the studies under the IND to which the hold applies.

21 C.F.R. 312.42. The July 30 trauma clinical hold letter was *not* about the BLA and did not need to be mentioned in the press release *about the July 30 BLA Letter*.

In addition, the July 30 trauma letter was *virtually identical* to the July 30 BLA Letter in terms of the questions asked. The first 14 pages of the trauma letter are verbatim questions

[5] What others *allegedly said* the Letter was, whether Franklin Stephenson or a lawyer who did not read it, does not matter. First, the press release was still accurate in saying "completed review" because that is what the official agency writing said. Off-hand remarks cannot control. Second, the label was not material for the reason just discussed and for the reasons set forth in Defendants' opening brief.

copied from the first 13 pages of the BLA letter. Compare SEC Ex. 49, pp. 1-14 with SEC Ex. 48, pp. 1-13. The trauma letter made *two* comments on the last page that did not appear in the July 30 BLA Letter. One comment was about stratum specific randomization for patients over 75 and the second comment asked Biopure to submit some final study reports to supplement earlier abstracts. *See* SEC's Appendix, Ex. 49, p. 14. There was nothing material about those two comments in a different letter about a different proposed protocol for a different indication that was omitted from the press release about the *BLA Letter*.

II. The August 1 Press Release Did Not Misstate Material Facts.

Plaintiff contends the press release contained two "false statements:" that the Letter "focuses primarily" on clarification of clinical and preclinical data and that Mr. Moore was "encouraged," as he was quoted as saying, because "FDA finished its review and provided comprehensive feedback in advance of the final action due date" and FDA was "encouraging" Biopure to work with them to complete the approval process as quickly as possible.

As described above, the Letter asks Biopure to "explain," "clarify," and "comment" on data repeatedly. The assertion in the release that the July 30 BLA Letter "focuses primarily" on clarification of clinical and preclinical data will withstand judicial scrutiny. The Letter does just that.

As for Mr. Moore's quote, the *fact* in the quote, that the July 30 BLA Letter arrived 30 days in advance of the expected date, is undisputed. The Letter was dated and sent on July 30, 2003 - thirty days before the expected date of August 29, 2003. Plaintiff is left to claim fraud on whether Mr. Moore was "encouraged" by that at the time. As it must under Fed. R. Civ. P. 56(e) in opposing a motion for summary judgment, the SEC has offered nothing in its Statement of Facts to demonstrate that Mr. Moore did not believe these opinions when quoted and it cannot

because Mr. Moore testified to the SEC that he was encouraged and optimistic when he made the statements. Interpreting an early arrival as encouraging (with the fact the letter did *not* request additional trials) is certainly not *per se* unreasonable. As such, Plaintiff lacks the core element of *any* fraud claim: an untrue statement.

Moreover, the statements are not guarantees of FDA approval and are not actionable. *See In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 118 (D. Mass. 1999) (quoting *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 964 (D. Md. 1995)) ("While it is true that a 'guarantee' of approval of a product by a federal agency might be actionable, … the key word is 'guarantee.' Mere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable"); *Noble Asset Management v. Allos, Therapeutics, Inc.*, 1:04-cv-01030-RPM (D. Colo. Oct. 10, 2005) (optimistic statements concerning FDA approval not actionable; there was no statement guaranteeing approval). They are soft, forward-looking and not actionable.

Indeed, in this case, the quoted statements were not even optimistic about FDA *approval*. They were optimistic about FDA's willingness to *work with* the Company *in the approval process*. *See* Buhlman Aff., Ex. A ("We're encouraged that FDA has finished its review and provided comprehensive feedback" and "FDA is encouraging us to work with them"). *See Shaw v. Digital Equipment Corp.*, 82 F.3d 1194, 1217 (1st Cir. 1996) *superceded by statute on other grounds as recognized in Greebel v. FTP Software, Inc.*, 194 F.3d 185 (1st Cir. 1999) ("Courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace--loosely optimistic statements that are so vague, so lacking in specificity, or so

clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available").

Conclusion

For these reasons, Defendants should be granted partial summary judgment on all claims that Biopure's August 1, 2003 press release was misleading, as requested in their Motion for Partial Summary Judgment.

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Certificate of Service

I, Michael D. Blanchard, hereby certify that on February 16, 2006, a true and correct copy of the foregoing Reply Memorandum In Support of Defendants' Motion for Partial Summary Judgment was electronically upon counsel of record for each other party.

/s/ Michael D. Blanchard
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